each formula of specially denatured alcohol involved; explain why the use of the substitute denaturant, or the variation from specifications, as the case may be, is necessary; and include, as applicable, either the identity of the approved denaturant for which substitution is desired and the identity of the substitute denaturant (including the name of the manufacturer) or the identity of the prescribed specifications and the proposed variation from those specifications. The application shall be accompanied by an 8-ounce sample of the proposed denaturing material for analysis.

§ 21.92 Denaturants listed as U.S.P. or N.F.

Denaturing materials and products listed in this part as ''U.S.P.'' or ''N.F.'' shall meet the specifications set forth in the current United States Pharmacopoeia or National Formulary, or the latest volume of these publications in which the denaturants appeared as official preparations.

§ 21.93 Acetaldehyde.

(a) *Aldehyde content (as acetaldehyde).* Not less than 95.0 percent by weight.

(b) *Color.* Colorless.

(c) *Odor.* Characteristic pungent, fruity odor.

(d) *Specific gravity at 15.56 °/15.56 °C.* Not less than 0.7800.

§ 21.94 Acetaldol.

(a) *Purity.* Not less than 90 percent by weight acetaldol as determined by the following method:

Dissolve 15 grams of the acetaldol in distilled water and dilute to 1 liter in a volumetric flask. Transfer 5 ml of this solution to a 250 ml glass-stoppered flask containing 25 ml distilled water. Add 25 ml of a freshly prepared 1 percent sodium bisulfite solution. Prepare a blank omitting the acetaldol solution. Place the flasks in a dark place away from excessive heat or cold and allow to stand six hours. Remove flasks and titrate free bisulfite with 0.1 N iodine solution using starch indicator.

Percent acetaldol by weight=(ml blank − ml test)×200×0.44/weight of sample

Titrations in excess of 100 percent may be obtained if the sample contains appreciable amounts of acetaldehyde.

(b) *Specific gravity at 20 °C.* 1.098 to 1.105.

§ 21.95 Ammonia, aqueous.

(a) *Alkalinity.* Strongly alkaline to litmus.

(b) *Ammonia content.* 27 to 30 percent by weight. Accurately weigh a glass-stoppered flask containing 25 ml of water, add about 2 ml of the sample, stopper, and weigh again. Add methyl red indicator, and titrate with 1 N sulfuric acid. Each ml of 1 N sulfuric acid is equivalent to 17.03 mg of NH_3

(c) *Color.* Colorless liquid.

(d) *Non-volatile residue.* 2 mg maximum. Dilute a portion of the sample with 1½ times its volume of distilled water. Evaporate 10 ml of this product to dryness in a tared platinum or porcelain dish. Dry residue at 105 °C. for 1 hour, cool and weigh.

(e) *Odor.* Characteristic (exceedingly pungent).

(f) *Specific gravity at 20 °/4 °C.* 0.8920 to 0.9010.

§ 21.96 Benzene.

(a) *Distillation range.* (For applicable ASTM method, see 1980 Annual Book of ASTM Standards, Part 29, page 573, Standard No. D 836–77; for incorporation by reference, see §21.6(b).) When 100 ml of benzene are distilled by this method, not more than 1 ml should distill below 77 °C., and not less than 95 ml below 85 °C.

(b) *Odor.* Characteristic odor.

(c) *Specific gravity at 15.6 °/15.6 °C.* 0.875 to 0.886.

(d) *Water solubility.* When 10 ml of benzene are shaken with an equal volume of water in a glass-stoppered bottle, graduated to 0.1 ml, and allowed to stand 5 minutes to separate, the upper layer of liquid shall measure not less than 9.5 ml.

§ 21.97 Bone oil (Dipple's oil).

(a) *Color.* The color shall be a deep brown.

(b) *Distillation range.* When 100 ml are distilled in the manner described for pyridine bases, not more than 5.0 ml should distill below 90 °C.

(c) *Pyrrol reaction.* Prepare a 1.0 percent solution of bone oil in 95 percent